Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparative effects of high and low intensity resistance training on balance and fatigue perception in patients with Parkinson’s Disease

Protocol summary

Study aim
To determine the comparative effects of high and low intensity resistance training on balance and fatigue perception in patients with Parkinson's disease.

Design
Parallel group, single-blind, randomized controlled trial on 44 individuals

Settings and conduct
A study was conducted in Physiotherapy Department at District Headquarter Hospital (DHQ) Sheikhupura. A single blinded study and participants were blinded through chit method.

Participants/Inclusion and exclusion criteria
Inclusion criteria: both male and female; 50-65 years old people; Parkinson's disease. Exclusion criteria: cognitive impairments; diagnosed by any other neurological conditions.

Intervention groups
Patients allocated to Group A performed a low-intensity exercise program that included breathing, stretching, and relaxation in a sitting position twice a week for 12 consecutive weeks. In contrast, Participants located in Group B went through high-intensity exercises with Thera-bands twice a week for 12 consecutive weeks with individualized progression. Each session ended up in 60 min. The standard training program included a 5-10 min warm-up session, core activities, and a 5-min cool-down. Outcomes were measured by two scales, Mini-Bestest and Revised Piper Fatigue Scale.

Main outcome variables
Dynamic balance (sensory orientation; dynamic gate; postural instability; anticipatory transitions); Fatigue perception (behavioral/severity; affective meaning; sensory; cognitive/mood).

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211107052992N1**
Registration date: **2022-09-18, 1401/06/27**
Registration timing: **retrospective**

Last update: **2022-09-18, 1401/06/27**
Update count: **0**

Registration date
2022-09-18, 1401/06/27

Registrant information
Name
Rida Naqvi
Name of organization / entity
University of Lahore, Lahore (Pakistan)
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Pakistan
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-12-04, 1399/09/14

Expected recruitment end date
2020-12-30, 1399/10/10

Actual recruitment start date
2020-12-04, 1399/09/14

Actual recruitment end date
2020-12-30, 1399/10/10

Trial completion date
2021-03-30, 1400/01/10

Scientific title
Comparative effects of high and low intensity resistance training on balance and fatigue perception in patients with Parkinson’s Disease

Public title
Comparative effects of high and low intensity resistance training on balance and fatigue perception in patients with Parkinson’s Disease
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
use stable medicine able to walk 10 m without any kind of assistant either by a person or a walking frame.
Exclusion criteria:
cognitive impairment (Mini-Mental State Examination score lower than 24) comprehension deficits that prevented them from following verbal commands have visual or acoustic limitations diagnosed by any neurological condition other than PD, or other clinical comorbidities that affect the gait
Age
From **50 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **44**
More than 1 sample in each individual
Number of samples in each individual: **3**
Samples were taken 3 times from both group. First time as a baseline. 2nd time after 6 weeks of treatment and third time again after 6 weeks of treatment
Actual sample size reached: **44**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization method used. Both group A and B randomized. Participants with Parkinson's Disease in both A and B group randomly selected after matching inclusion criteria through chit method. Random sequence was built by appointing Even numbers to the group A and odd numbers to group B.
Blinding (investigator's opinion)
Single blinded
Blinding description
Participants of both groups were blinded in this study through chit method. We had 2 chits on one Group A were written and on other Group B and once they matched the inclusion criteria we gave them both sealed chit and said to choose one. We share general information about the intervention and study protocol with participants of both groups. Participants were informed that they would be randomly allocated into one of the groups and would receive different exercises and Physiotherapy interventions as treatment. Only information about high and low-intensity exercises. After group allocation, they were informed about the detailed intervention plan of their group. Timing of sessions of both groups participants were different to avoid the unintended meetup of the participants.
Placebo
Not used
Assignment
Other
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of University of Lahore
Street address
University of Lahore, 1 km, Defence Road, Off Bhobatian Chowk, Lahore
City
Lahore
Postal code
55150
Approval date
2020-12-03, 1399/09/13
Ethics committee reference number
IRB-UOL-FAHS/798/2020

Health conditions studied

1

Description of health condition studied
Parkinson's Disease
ICD-10 code
G20
ICD-10 code description
Parkinson's Disease

Primary outcomes

1

Description
Balance and Fatigue
Timepoint
baseline, 6 weeks after intervention and 12 weeks after intervention
Method of measurement
Mini-BESTest and Piper Fatigue Scale

Secondary outcomes

empty

Intervention groups

1

Description
Group A (Intervention group): 22 patients allocated to

the Group A performed low-intensity exercise program which include breathing, stretching and relaxation activities in a sitting position twice a week for 12 consecutive weeks. Each session ended-up in 60 min. The standard training program included 5-10 min warm-up session, core activities and 5-min cool-down.

Category

Rehabilitation

2

Description

Group B (Intervention group): 22 participants allocated in Group B randomly. Participants allocated to the Group B gone through high intensity resistance training program with thera-bands twice a week for 12 consecutive weeks with individualized progression. Each session ended-up in 60 min. The standard training program included 5-10 min warm-up session, core activities and 5-min cool-down.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

District Headquarter Hospital

Full name of responsible person

Dr. Imran Manzoor Bhatti

Street address

PX6H+PGF, Sheikhupura, Punjab

City

Sheikhupura

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39350

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Web page address

https://dhqsheikhupura.punjab.gov.pk/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

The University of Lahore

Full name of responsible person

Dr. Ashfaq Ahmed

Street address

1-Km Defence Road، near Bhuptian Chowk، Lahore, Punjab

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ashfaq.ahmed@uipt.uol.edu.pk

Web page address

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

The University of Lahore

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Foreign

Category of foreign source of funding

Sponsor: country of origin

Country of origin

PK

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

University of Lahore

Full name of responsible person

Rida Naqvi

Position

Postgraduate Resident

Latest degree

Bachelor

Other areas of specialty/work

Physiotherapy

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
"There is no further information"

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available